REMARKS

This is a full and timely response to the outstanding non-final Office Action mailed September 3, 2009. Reconsideration and allowance of the application and pending claims are respectfully requested.

I. Specification Objections

The specification was objected to for failing to include a reference to prior related patent applications. In response to the objection, Applicant has amended the specification to specifically reference those applications along with a petition requesting permission to make the amendment. Applicant believes that the amendment and petition overcome the objection.

II. Claim Rejections - 35 U.S.C. § 103(a)

Claims 1-28 and 31-45 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over *Phillips* (U.S. Pub. No.: 2002/0045646) in view of *Bergstrand, et al.* ("Bergstrand," U.S. Pat. No. 5,817,338) and *Chen* (U.S. Pub. No.: 2001/0006649).

As has been acknowledged by the Court of Appeals for the Federal Circuit, the U.S. Patent and Trademark Office ("USPTO") has the burden 35 U.S.C. § 103 to establish obviousness by showing objective teachings in the prior art or generally available knowledge of one of ordinary skill in the art that would lead that individual to the claimed invention. *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q. 2d 1596, 1598 (Fed. Cir. 1988). The key to supporting an allegation of obviousness under 35 U.S.C. § 103 is the clear articulation of the reasons why the Examiner believes that claimed

invention would have been obvious. *See* MPEP § 2141. As stated by the Supreme Court, "[r]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR v. Teleflex*, 550 U.S. at 398, 82 USPQ2d 1385 (quoting *In re Kahn,* 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)). Applicant respectfully submits that the Examiner has not established with clearly articulated reasons that Applicant's claims are obvious in view of the prior art. Applicant discusses those claims below.

1. Claims 1-28

Applicant's independent claim 1 now provides as follows:

1. An oral pharmaceutical composition comprising multiple populations of at least one of beads, pellets, tablets and granules provided in a capsule, the composition comprising:

(i) a first population of a pharmaceutical active comprising a pharmaceutical active substance releasable at a first rate, wherein the first population is selected from the group consisting of: a population of beads, a population of pellets, a population of tablets, a population of granules, and any combination thereof;

(ii) a second population of a pharmaceutical active comprising a pharmaceutical active substance releasable at a second rate, wherein the second population is selected from the group consisting of: a population of beads, a population of pellets, a population of tablets, a population of granules, and any combination thereof; and

(iii) a population of a basic substance, wherein the population of the basic substance excludes said pharmaceutical active substance, the

population of the basic substance being selected from the group consisting of: a population of beads, a population of pellets, a population of tablets, a population of granules, and any combination thereof.

Claim 1 clearly describes a composition that comprises *three separate and distinct populations*: (i) a population of a pharmaceutical active substance releasable at a first rate, (ii) a population of a pharmaceutical active substance releasable at a second rate, and (iii) a population of a basic substance that excludes the pharmaceutical active substance. Each population is independently formulated as beads, pellets, tablets, granules, or combinations thereof. Therefore, the pharmaceutical active and the basic substance are *not* mixed together in a single population. Applicant asserts that none of the applied references discloses or suggests such a composition.

Example VI of the Phillips reference was identified in the Office Action for support in rejecting claim 1. In that example, Phillips describes a "combination tablet." *Phillips*, paragraph 0176. The tablet includes an inner core that is formed by mixing omeprazole powder with sodium bicarbonate, and an outer core of omeprazole enteric-coated granules mixed with known binders and excipients. *Phillips*, paragraph 0176. Example VI therefore fails to disclose or suggest a composition that contains *separate populations* of a pharmaceutical active substance and a basic substance. Instead, that example only describes directly mixing omeprazole and sodium bicarbonate in a single population. Moreover, Example VI does not disclose or suggest a composition that contains both a population of a pharmaceutical active substance releasable *at a first rate*, and a population of a pharmaceutical active substance releasable *at a second rate*.

The Bergstrand reference is similarly deficient. Disclosed by Bergstrand are tablets that are formed by compressing enteric coated omeprazole units into tablets. *Bergstrand*, column 3, lines 13-19. Although Bergstrand indicates that the units can be optionally covered with one or more separating layers, such as pH-buffering compound layers, such an arrangement is not a composition that includes *separate populations* of a pharmaceutical active substance and a basic substance. Moreover, like Phillips, Bergstrand is silent as to a composition that contains both a population of a pharmaceutical active substance releasable *at a first rate*, and a population of a pharmaceutical active substance releasable *at a second rate*.

Turning to the Chen reference, Chen discloses a composition that comprises a core of powder/granules of an active drug that is filled into a hard gelatin capsule. *Chen*, paragraph 0040. Therefore, Chen also fails to disclose or suggest a population of a pharmaceutical active substance releasable at a first rate, a population of a pharmaceutical active substance releasable at a second rate, and a population of a basic substance.

Applicant notes that by providing separate and distinct populations of an active agent and a basic substance, as claimed by Applicant, each population can be released independently of the others at different times. This is described in Applicant's specification in the paragraph bridging pages 8 and 9. In contrast, the mixtures of basic substance and active agent described in the applied references are not capable of such independent release.

In view of the above discussion, it is clear that the applied references do not, either alone or in combination, disclose or suggest the composition of matter recited in

claim 1. Applicant therefore requests that the rejections of claim 1 and its dependents be withdrawn.

2. Claims 31-45

Applicant's independent claim 31 provides as follows:

31. An oral pharmaceutical composition comprising multiple populations of at least one of beads, pellets, tablets and granules provided in a capsule, the composition comprising:

(i) a population of a pharmaceutical active, wherein the population of the pharmaceutical active is selected from the group consisting of: a population of beads, a population of pellets, a population of tablets, a population of granules, and any combination thereof;

(ii) a population of enteric coated pharmaceutical active, wherein the population of enteric coated pharmaceutical active is selected from the group consisting of: a population of beads, a population of pellets, a population of tablets, a population of granules, and any combination thereof;

(iii) a population of a basic substance, wherein the population of the basic substance excludes said pharmaceutical active, the population of the basic substance being selected from the group consisting of: a population of beads, a population of pellets, a population of tablets, a population of granules, and any combination thereof; and

(iv) a population of enteric coated basic substance, wherein the population of enteric coated basic substance excludes said pharmaceutical active, the population of enteric coated basic substance being selected from the group consisting of: a population of beads, a population of pellets, a population of tablets, a population of granules, and any combination thereof.

Claim 31 clearly describes a composition that comprises *four separate and distinct populations*: (i) a population of a pharmaceutical active, (ii) a population of enteric coated pharmaceutical active, (iii) a population of a basic substance, and (iv) a population of enteric coated basic substance.

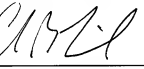
As described above in relation to claim 1, none of the applied Phillips, Bergstrand, and Chen references disclose or suggest a composition that comprises separate populations of a pharmaceutical active and a basic substance. Therefore, those references fail to render claim 31 obvious, which likewise recites separate populations of a pharmaceutical active and a basic substance. Applicant therefore requests that the rejections of claim 31 and its dependents also be withdrawn.

As a further matter, Applicant notes that none of the applied references discloses or suggests a composition that not only includes separate populations of a pharmaceutical active and a basic substance, but *additionally* includes a population of enteric coated pharmaceutical active and a population of enteric coated basic substance. Claim 31 and its dependents are further allowable for that reason.

CONCLUSION

Applicant respectfully submits that Applicant's pending claims are in condition for allowance. Favorable reconsideration and allowance of the present application and all pending claims are hereby courteously requested. If, in the opinion of the Examiner, a telephonic conference would expedite the examination of this matter, the Examiner is invited to call the undersigned attorney at (770) 933-9500.

Respectfully submitted,



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